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<p>(54) Title: A FILTER ELEMENT WITH RETRACTABLE GUIDEWIRE TIP</p> <div data-bbox="373 1092 1364 1323"> </div> <p>(57) Abstract</p> <p>A medical guidewire assembly comprises a guidewire (30) having a flexible tip (32). A medical device such as a collapsible filter (31) for use as an embolic protection device is mounted on the guidewire (30). The filter (31) is advanced through a body lumen with the guidewire tip (32) extending distally. At a first location the filter (31) is advanced relative to the tip (32) to a location which is distally advanced from the first location. Placement of the filter (31) in an optimal distal location is thereby achieved.</p>		

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“A FILTER ELEMENT WITH RETRACTABLE GUIDEWIRE TIP”

This invention relates to a filter element for a transcatheter embolic protection device.

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Introduction

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The invention is particularly concerned with filter elements for transcatheter embolic protection devices of the type described in our WO-A-9923976. One type of such embolic filter essentially comprises a filter body mounted on an associated collapsible support frame which can be collapsed against the guidewire by means of a catheter for deployment of the filter through a patient's vascular system. Upon retraction of the catheter the support frame and filter body expand outwardly from the guidewire across a blood vessel within which the filter is positioned to filter blood flowing through the blood vessel.

20

One problem with the filter device is that there is a guidewire tip on the distal end which is required for guiding the filter into a desired position. The guidewire tip needs to be relatively long to provide a smooth tip transition. However, the guidewire distal tip may interfere with the optimal placement of the filter element.

The present invention is directed towards overcoming this problem.

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Statements of Invention

According to the invention there is provide a medical guidewire assembly comprising:-

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a guidewire having a flexible tip at a distal end of the guidewire;

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a medical device mounted near the distal end of the guidewire proximally of the tip, the medical device being movable relative to the tip for adjustment of the amount of the tip extending distally of the medical device;

5

and means to limit the movement of the medical device relative to the tip.

In a preferred embodiment of the invention the means to limit the movement of the medical device comprise one or more stiff limiting elements.

10

Preferably at least one limiting element is provided on the guidewire. The limiting element may be fixedly mounted to the guidewire. Alternatively, the limiting element is slidably mounted on the guidewire. In this case preferably the assembly includes stop means to limit slidable movement of the limiting element relative to the guidewire. The stop means to limit slidable movement of the limiting element preferably comprises a pair of stops spaced axially apart along the guidewire. The stops may be provided by abutment surfaces formed in the guidewire.

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In a preferred embodiment of the invention at least one limiting element is mounted to the medical device. Preferably the limiting element is mounted to the medical device at the proximal end of the medical device. In one arrangement the limiting element is mounted intermediate proximal and distal ends of the medical device.

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In one embodiment of the invention at least one limiting element is stiff relative to the guidewire.

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Alternatively or additionally at least one limiting element is compliant relative to the guidewire.

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Preferably the medical device and the tip are slidable relative to each other. Ideally, the medical device has a receiver slot for reception of at least portion of the tip. In one embodiment of the invention the tip is fully retractable within the receiver slot.

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In a particularly preferred embodiment of the invention the medical device is a collapsible embolic filter mounted on a tubular sleeve which is slidably mounted on the guidewire adjacent the distal end of the guidewire, the sleeve having a bore through which the guidewire passes, said bore forming a receiver slot for reception
10 of the flexible tip of the guidewire which is at least partially retractable within the bore of the sleeve.

Preferably the tip is fully retractable within the bore of the sleeve.

15

In one embodiment a guidewire limiting element is mounted to the guidewire proximal of the embolic filter and a filter limiting element is mounted to the filter within the bore of the sleeve, the guidewire being movable relative to the filter between the first and second limiting elements. In this case preferably the guidewire has an abutment which is engagable with the filter limiting element
20 when the guidewire tip is retracted. In one embodiment the abutment is provided by a shoulder of the tip.

In one arrangement the filter limiting element is provided at a proximal end of the filter.

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In another arrangement the filter limiting element is provided intermediate proximal and distal ends of the filter.

In another embodiment of the invention a guidewire limiting element is mounted
30 to the guidewire intermediate proximal and distal ends of the filter and the filter

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has a proximal filter limiting element and a distal filter limiting element, the guidewire limiting element being movable with the guidewire between the proximal and distal filter limiting elements.

5 In one case the guidewire tip is retractable proximally of the distal filter limiting element.

10 Preferably the guidewire limiting element is movable on the guidewire. In this case the assembly includes stop means to limit slidable movement of the guidewire limiting element relative to the guidewire. The stop means may comprise a pair of stops spaced axially apart along the guidewire. The stops may be provided by abutment surfaces formed in the guidewire. In one embodiment the guidewire has a recessed portion of reduced diameter on which the guidewire limiting element is mounted.

15

In another aspect the invention provides an embolic protection device comprising:

a collapsible filter element mounted on a filter carrier for delivery through a vascular system of a patient;

20

the filter element being movable between a collapsed stored position against the filter carrier for movement through the vascular system, and an expanded position for occluding a blood vessel such that blood passing through the blood vessel is delivered through the filter element;

25

the filter element comprising a collapsible filter body having an inlet end and an outlet end;

30

the inlet end of the filter body having one or more inlet openings sized to allow blood and embolic material enter the filter body;

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the outlet end of the filter body having a plurality of outlet openings sized to allow through passage of blood but to retain undesired embolic material within the filter body;

5

the collapsible filter element being slidably mounted on the filter carrier for axial movement of the filter element along the filter carrier; and

10

means to limit the movement of the filter element relative to the filter carrier, the means being arranged to allow a distal end of the filter carrier to be substantially retracted into the filter element.

In one embodiment of the invention the means to limit the movement of the filter element comprise one or more limiting elements.

15

At least one limiting element is preferably provided on the filter carrier.

The limiting element may be fixedly mounted on the filter carrier.

20

Alternatively the limiting element is slidably mounted on the filter carrier. In this case the device preferably includes stop means to limit the movement of the limiting element relative to the filter carrier. The means to limit the movement of the limiting element may comprise a pair of stops spaced axially apart along the filter carrier. The stops may be provided by abutment surfaces formed on the filter carrier.

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In a preferred embodiment of the invention at least one limiting element is mounted to the filter element. The limiting element may be mounted to the filter element intermediate the proximal and distal ends of the filter element.

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In one embodiment of the invention at least one limiting element is stiff relative to the filter carrier. Alternatively or additionally at least one limiting element is compliant relative to the filter carrier.

- 5 The limiting element may be mounted to the filter element at the proximal end of the filter element.

- 10 In a particularly preferred embodiment of the invention the filter carrier is a guidewire. Preferably the distal end of the guidewire includes a guiding tip which may be substantially retracted into the filter element.

The invention also provides a method for positioning a medical device in a body lumen comprising the steps of:-

- 15 providing a medical guidewire assembly of the invention;
- advancing the assembly into a body lumen with the guidewire tip extending distally of the medical device to a first location;
- 20 moving the medical device relative to the tip to advance the medical device to a second location which is distally advanced from the first location.

Brief Description of the Drawings

- 25 The invention will be more clearly understood by the following description of some of the embodiments thereof, given by way of example only, with reference to the accompanying drawings, in which: -

- 30 Fig. 1 is partially sectioned elevational view of an embolic protection device;

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Fig. 2 is a schematic sectional elevational view of the embolic protection device of Fig. 1;

5 Fig. 3 is a detail sectional view of a portion of the device of Fig. 1;

Fig. 4 is a longitudinal cross sectional view of the device of Fig. 1;

10 Fig. 5 is a cross sectional view of a distal end of the device of Fig. 1;

Fig. 6 is a view on the line A-A in Fig. 4;

Fig. 7 is a perspective view of a filter body of the device of Figs. 1 to 6;

15 Fig. 8 is a side elevational view of the filter body of Fig. 7;

Fig. 9 is a view on a proximal end of the filter body;

20 Fig. 10 is a perspective view of a support frame of the device of Figs. 1 to 6;

Fig. 11 is a side elevational view of the support frame;

25 Fig. 12 is a perspective view illustrating the manufacture of the support frame;

Fig. 13 is a view of the support frame and filter body assembly;

30 Fig. 14 is a side partially cross sectional view of a filter body and guidewire according to one embodiment of the invention in one position of use;

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Fig. 15 is a side view similar to Fig. 14 in another position of use;

5 Fig. 16 is a side, partially cross sectional view of a filter body and guidewire according to another embodiment of the invention in one position of use;

Fig. 17 is a side view similar to Fig. 16 in another position of use;

10 Fig. 18 is a side partially cross sectional view of a filter body and guidewire according to a further embodiment of the invention in one position of use;

Figs. 19 and 20 are side views similar to Fig. 18 in other positions of use; and

15 Figs. 21 to 23 are side, partially cross sectional views of a filter body and guidewire according to a further embodiment of the invention in different positions of use.

Detailed Description

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Referring to Figs. 1 to 13 there is illustrated an embolic protection device as described in our WO-A-9923976 indicated generally by the reference number 100. The device 100 has a guidewire 101 with a proximal end 102 and a distal end 103. A tubular sleeve 104 is slidably mounted on the guidewire 101. A collapsible filter
25 105 is mounted on the sleeve 104, the filter 105 being movable between a collapsed stored position against the sleeve 104 and an expanded position as shown in the drawings extended outwardly of the sleeve 104 for deployment in a blood vessel.

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The sleeve 104 is slidable on the guidewire 101 between a pair of spaced-apart end stops, namely an inner stop 106 and an outer stop which in this case is formed by a spring tip 107 at the distal end 103 of the guidewire 101.

5 The filter 105 comprises a filter body 110 mounted over a collapsible support frame 111. The filter body 110 is mounted to the sleeve 104 at each end, the body 110 being rigidly attached to a proximal end 112 of the sleeve 104 and the body 110 being attached to a collar 115 which is slidable along a distal end 114 of the sleeve 104. Thus the distal end of the body 110 is longitudinally slidable along the sleeve 104. The support frame 111 is also fixed at the proximal end 112 of the sleeve 104. A distal end 116 of the support frame 111 is not attached to the sleeve 104 and is thus also free to move longitudinally along the sleeve 104 to facilitate collapsing the support frame 111 against the sleeve 104. The support frame 111 is such that it is naturally expanded as shown in the drawings and can be collapsed inwardly against the sleeve 104 for loading in a catheter 118 or the like.

20 The filter body 105 has large proximal inlet openings 117 and small distal outlet openings 119. The proximal inlet openings 117 allow blood and embolic material to enter the filter body, while, the distal outlet openings 119 allow through passage of blood but retain undesired embolic material within the filter body.

25 An olive guide 120 is mounted at a distal end of the sleeve 104 and has a cylindrical central portion 121 with tapered ends 122, 123. The distal end 122 may be an arrowhead configuration for smooth transition between the catheter and olive surfaces. The support frame 111 is shaped to provide a circumferential groove 125 in the filter body 110. If the filter is too large for a vessel, the body may crease and this groove 125 ensures any crease does not propagate along the filter.

- 10 -

Enlarged openings are provided at a proximal end of the filter body 110 to allow ingress of blood and embolic material into an interior of the body 110.

5 In use, the filter 105 is mounted in a collapsed state within a distal end of the catheter 118 and delivered to a deployment site. When the filter is correctly positioned the catheter 118 is retracted allowing the support frame 111 to expand expanding the filter body 110 across the vessel in which the filter is mounted. Blood and emboli can enter the enlarged openings at a proximal end of the filter body 110. The blood will pass through the filter body, however, the openings or
10 pores in the filter body are sized so as to retain the embolic material. After use, a retrieval catheter 18 is delivered along the guidewire 101 and slid over the filter 105 engaging the proximal inlet end 112 first to close the openings and then gradually collapsing the filter body against the sleeve 104 as the catheter 118 advances over the filter 105. Once the filter 105 is fully loaded in the catheter 118,
15 it can then be withdrawn.

It will be noted that a proximal end of the filter is fixed and a distal end of the filter is longitudinally movable along the sleeve to facilitate collapsing of the filter body.

20 Further, the catheter engages the proximal end of the filter body first thus closing the filter body inlet and preventing escape of embolic material from the filter body as the filter body is being collapsed.

25 The outer filter body 110 is preferably of a resilient biocompatible elastomeric material. The material may be a polyurethane based material. There are a series of commercially available polyurethane materials that may be suitable. These are typically based on polyether or polycarbonate or silicone macroglycols together with diisocyanate and a diol or diamine or alkanolamine or water chain extender.
30 Examples of these are described in EP-A-461,375 and US 5,621, 065. In addition,

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polyurethane elastomers manufactured from polycarbonate polyols as describe US 5,254,622 (Szycher) are also suitable.

5 The filter material may also be a biostable polycarbonate urethane article example of which may be prepared by reaction of an isocyanate, a chain extender and a polycarbonate copolymer polyol of alkyl carbonates. This material described in our WO-A-9924084. The filter material may be manufactured from a block and cut into a desired shape. However the filter is preferably formed by dipping a rod of desired geometry into a solution of the material which coats the
10 rod. The rod is then dissolved. The final geometry of the filter may be determined in the dipping step or the final geometry may be achieved in a finishing operation. Typically the finishing operations involve processes such as mechanical machining operations, laser machining or chemical machining.

15 The filter body is of hollow construction and is formed as described above by dipping a rod in a solution of polymeric material to coat the rod. The rod is then dissolved, leaving a hollow body polymeric material. The rod may be of an acrylic material which is dissolved by a suitable solvent such as acetone.

20 The polymeric body thus formed is machined to the shape illustrated in Figs. 1 to 13. The final machined filter body comprises an inlet or proximal portion 210 with a proximal neck 212, and outlet or distal portion 213 with a distal neck 214, and an intermediate portion 215 between the proximal and distal portions.

25 The inlet holes 117 are provided in the proximal portion 210 which allow the blood and embolic material to flow into the filter body. In this case the proximal portion 210 is of generally conical shape to maximise the hole size.

30 The intermediate portion 215 is also hollow and in this case is of generally cylindrical construction. This is important in ensuring more than simple point

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contact with the surrounding blood vessel. The cylindrical structure allows the filter body to come into soft contact with the blood vessel to avoid damaging the vessel wall.

5 The intermediate portion 215 is provided with a radial stiffening means, in this case in the form of a radial strengthening ring or rim 220. The ring 220 provides localised stiffening of the filter body without stiffening the material in contact with the vessel. Such an arrangement provides appropriate structural strength so that line apposition of the filter body to the vessel wall is achieved. It is expected that
10 other geometries of stiffening means will achieve a similar result.

The tubular intermediate portion 215 is also important in maintaining the stability of the filter body in situ to retain captured emboli and to ensure that flow around the filter is minimised. For optimum stability we have found that the ratio of the
15 axial length of the intermediate portion 215 of the filter body to the diameter of the intermediate portion 215 is preferably at least 0.5 and ideally greater than 1.0.

The collapsible support frame 111 has four foldable arms 290 which are collapsed for deployment and upon release extend outwardly to expand the filter body 110.

20 The support frame 111 can be manufactured from a range of metallic or polymeric components such as a shape memory alloy like nitinol or a shape memory polymer or a shaped stainless steel or metal with similar properties that will recover from the deformation sufficiently to initiate opening of the filter body 110.

25 The support frame may be formed as illustrated in Fig. 12 by machining slots in a tube 291 of shape memory alloy such as nitinol. On machining, the unslotted distal end of the tube forms a distal collar 293 and the unslotted proximal end of the tube forms a proximal collar 294. In use, the distal collar 293 is slidably
30 moveable along the tubular sleeve 104 which in turn is slidably mounted on the

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guidewire 101 for deployment and retrieval. The proximal collar 294 is fixed relative to the tubular sleeve 104.

5 To load the filter the sub assembly of the support frame and filter body is pulled back into the catheter 118 to engage the distal stop 107. The support arms 290 are hinged inwardly and the distal collar 293 moves forward along the tubular sleeve 104. As the support arms 290 enter the catheter 118 the filter body 110 stretches as the filter body collar 115 slides along the tubular sleeve 104 proximal to the olive 120. On deployment, the catheter 118 is retracted proximally along the
10 guidewire 101 initially bringing the collapsed filter assembly with it until it engages the proximal stop 106. The catheter sleeve then begins to pull off the filter, freeing the support arms 290 to initiate opening of the filter body to appose the vessel wall.

15 For retrieval, a retrieval catheter is introduced by sliding it over the guidewire 101 until it is positioned at the proximal end of the filter body and support frame. Pulling the guidewire 101 will initially engage the distal stop 107 with the filter element and begin to pull it into the retrieval catheter. The initial travel into the delivery catheter acts to close the proximal openings of the filter element, thus
20 entrapping the embolic load. As the filter continues to be pulled back the filter body and the support frame are enveloped in the retrieval catheter. The collapsed filter may then be removed from the patient.

Referring to Figs. 14 and 15 there is illustrated a medical guidewire assembly
25 according to one embodiment of the invention. A filter 31 is mounted on a guidewire 30 and projecting from the distal end of the guidewire 30 is a guidewire tip 32. The guidewire tip 32 is slidable in a bore 38 in a sleeve 39 of the filter 31. When the filter 31 is being manoeuvred into place the guidewire tip 32 facilitates the manoeuvring of the filter device. By advancing and retracting the tip 32
30 relative to the filter assembly 31 it is possible to manoeuvre the guidewire tip 32

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around various portions of the anatomy, for example, where it is particularly tortuous, or where the guidewire tip 32 has to cross lesions. The tip 32 can be partially retracted to give a stiffer tip, or can be fully retracted in the deployment position, Fig. 15.

5

The guidewire 30 is slidable between a proximal guidewire limiting element 35 on the guidewire 30 and a filter limiting element 37 provided at a proximal end of the filter 31. A stop defined by a shoulder 36 of the tip 32 is engagable against the limiting element 37.

10

The proximal limiting element 35 and the filter limiting element 37 are of a relatively stiff material, such that upon engagement of the filter 31 with the proximal limiting element 35, or the shoulder 36 with the filter limiting element 37, the limiting elements 35, 37 do not deform. In this way the movement of the filter 31 relative to the guidewire tip 32 is accurately controlled.

15

One or both of the limiting elements 35, 37 may be of a compliant material. This feature will assist in ensuring that the flexibility of the filter is not affected by the limiting elements.

20

Referring to Figs. 16 and 17 there is illustrated a medical guidewire assembly including a filter 42, which is similar to the filter 31 of Figs. 14 and 15, and the same reference numerals are used to denote similar elements in Figs. 16 and 17. In this case the guidewire 30 is slidable between a proximal limiting element 35 on the guidewire 30 and a filter limiting element 40 positioned intermediate the proximal and distal ends of the filter 42. A distal stop defined by a shoulder 36 of the tip 32 is engagable against the filter limiting element 40.

25

Referring to Figs. 18 to 20 there is illustrated a medical guidewire assembly including a filter 50, which is similar to filters 31 and 42 of Figs. 14 to 17, and the

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same reference numerals are used to denote similar elements in Figs. 18 to 20. In this arrangement a guidewire limiting element 51 is rigidly fixed to the guidewire 30 proximal of the tip 32, the filter 50 being mounted on the guidewire 30 so that the limiting element 51 is intermediate the proximal and distal ends of the filter 50. The guidewire 30 is slidable between a distal limiting element defined by a proximal shoulder 53 of the filter 50 which is engagable against the guidewire limiting element 51, and a proximal limiting element defined by a distal shoulder 52 of the filter 50 which is engagable against the guidewire limiting element 51. In this arrangement there is no obstruction to advancement of another medical device over the guidewire 30 to approach the filter 50 from the proximal direction.

Referring to Figs. 21 to 23 in an alternative embodiment of the invention, the guidewire limiting element 51 is slidably mounted within a recess 53 provided on the guidewire 30, the movement of the limiting element 51 relative to the guidewire 30 being limited between a proximal stop provided by a shoulder 55 of the recess and a distal stop provided by a shoulder 54 provided by the guidewire tip 32. This arrangement provides an even greater degree of freedom for movement of the guidewire 30 relative to the filter.

The filter may be placed over or beyond the distal guidewire tip. Thus, the invention facilitates the optimal placement of a filter device in the limited vasculature space available.

Other medical devices may be advanced over the guidewire to approach the filter from the proximal direction without obstruction. Such devices may be for use in performing angioplasty procedures, stenting and the like. Ready access is also provided to perform emergency procedures such as snaring of a medical device or part, and lysis for treatment of a blood clot.

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It will be appreciated that while the invention has been described in relation to an embolic protection device it may also be applied to medial guidewire assemblies for placement of other medical devices.

- 5 The invention is not limited to the embodiments hereinbefore described which may be varied in both construction and detail.

Claims

1. A medical guidewire assembly comprising :-
 - 5 a guidewire having a flexible tip at a distal end of the guidewire;

a medical device mounted near the distal end of the guidewire proximally of the tip, the medical device being movable relative to the tip for adjustment of the amount of the tip extending distally of the medical device;
10

and means to limit the movement of the medical device relative to the tip.
- 15 2. A medical guidewire assembly as claimed in claim 1 wherein the means to limit the movement of the medical device comprise one or more stiff limiting elements.
- 20 3. A medical guidewire assembly as claimed in claim 2 wherein at least one limiting element is provided on the guidewire.
4. A medical guidewire assembly as claimed in claim 3 wherein the limiting element is fixedly mounted to the guidewire.
- 25 5. A medical guidewire assembly as claimed in claim 3 wherein the limiting element is slidably mounted on the guidewire.
6. A medical guidewire assembly as claimed in claim 5 including stop means to limit slidable movement of the limiting element relative to the
30 guidewire.

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- 5
7. A medical guidewire assembly as claimed in claim 6 wherein the stop means to limit slidable movement of the limiting element comprises a pair of stops spaced axially apart along the guidewire.
8. A medical guidewire assembly as claimed in claim 7 wherein the stops are provided by abutment surfaces formed in the guidewire.
- 10
9. A medical guidewire assembly as claimed in any of claims 2 to 8 wherein at least one limiting element is mounted to the medical device. C
10. A medical guidewire assembly as claimed in claim 9 wherein the limiting element is mounted to the medical device at the proximal end of the medical device.
- 15
11. A medical guidewire assembly as claimed in claim 10 or 11 wherein the limiting element is mounted intermediate proximal and distal ends of the medical device.
- 20
12. A medical guidewire assembly as claimed in any of claims 2 to 11 wherein at least one limiting element is stiff relative to the guidewire. C
13. A medical guidewire assembly as claimed in any of claims 2 to 12 wherein at least one limiting element is compliant relative to the guidewire.
- 25
14. A medical guidewire assembly as claimed in any preceding claim wherein the medical device and the tip are slidable relative to each other.

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15. A medical guidewire assembly as claimed in any preceding claim wherein the medical device has a receiver slot for reception of at least portion of the tip.
- 5 16. A medical guidewire assembly as claimed in claim 15 wherein the tip is fully retractable within the receiver slot.
- 10 17. A medical guidewire assembly as claimed in any preceding claim wherein the medical device is a collapsible embolic filter mounted on a tubular sleeve which is slidably mounted on the guidewire adjacent the distal end of the guidewire, the sleeve having a bore through which the guidewire passes, said bore forming a receiver slot for reception of the flexible tip of the guidewire which is at least partially retractable within the bore of the sleeve.
- 15 18. A medical guidewire assembly as claimed in claim 17 wherein the tip is fully retractable within the bore of the sleeve.
- 20 19. A medical guidewire assembly as claimed in claim 17 or 18 wherein a guidewire limiting element is mounted to the guidewire proximal of the embolic filter and a filter limiting element is mounted to the filter within the bore of the sleeve, the guidewire being movable relative to the filter between the first and second limiting elements.
- 25 20. A medical guidewire assembly as claimed in claim 19 wherein the guidewire has an abutment which is engagable with the filter limiting element when the guidewire tip is retracted.
- 30 21. A medical guidewire assembly as claimed in claim 20 wherein the abutment is provided by a shoulder of the tip.

- 20 -

22. A medical guidewire assembly as claimed in any of claims 19 to 21 wherein the filter limiting element is provided at a proximal end of the filter.
- 5
23. A medical guidewire assembly as claimed in any of claims 19 to 21 wherein the filter limiting element is provided intermediate proximal and distal ends of the filter.
- 10
24. A medical guidewire assembly as claimed in claim 17 or 18 wherein a guidewire limiting element is mounted to the guidewire intermediate proximal and distal ends of the filter and the filter has a proximal filter limiting element and a distal filter limiting element, the guidewire limiting element being movable with the guidewire between the proximal and distal filter limiting elements.
- 15
25. A medical guidewire assembly as claimed in claim 24 wherein the guidewire tip is retractable proximally of the distal filter limiting element.
- 20
26. A medical guidewire assembly as claimed in claim 24 wherein the guidewire limiting element is movable on the guidewire.
- 25
27. A medical guidewire assembly as claimed in claim 26 including stop means to limit slidable movement of the guidewire limiting element relative to the guidewire.
28. A medical guidewire assembly as claimed in claim 27 wherein the stop means comprises a pair of stops spaced axially apart along the guidewire.

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29. A medical guidewire assembly as claimed in claim 28 wherein the stops are provided by abutment surfaces formed in the guidewire.
- 5 30. A medical guidewire assembly as claimed in any of claims 27 to 29 wherein the guidewire has a recessed portion of reduced diameter on which the guidewire limiting element is mounted.
- 10 31. A medical guidewire assembly substantially as hereinbefore described with reference to the accompanying drawings.
32. An embolic protection device comprising:
- 15 a collapsible filter element mounted on a filter carrier for delivery through a vascular system of a patient;
- the filter element being movable between a collapsed stored position against the filter carrier for movement through the vascular system, and an expanded position for occluding a blood vessel such that blood passing through the blood vessel is delivered through the filter element;
- 20 the filter element comprising a collapsible filter body having an inlet end and an outlet end;
- 25 the inlet end of the filter body having one or more inlet openings sized to allow blood and embolic material enter the filter body;
- 30 the outlet end of the filter body having a plurality of outlet openings sized to allow through passage of blood but to retain undesired embolic material within the filter body;

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the collapsible filter element being slidably mounted on the filter carrier for axial movement of the filter element along the filter carrier; and

5

means to limit the movement of the filter element relative to the filter carrier, the means being arranged to allow a distal end of the filter carrier to be substantially retracted into the filter element.

- 10 33. An embolic protection device as claimed in claim 32 wherein the means to limit the movement of the filter element comprise one or more limiting elements.
- 15 34. An embolic protection device as claimed in claims 32 or 33 wherein at least one limiting element is provided on the filter carrier.
35. An embolic protection device as claimed in claim 34 wherein the limiting element is fixedly mounted on the filter carrier.
- 20 36. An embolic protection device as claimed in claim 34 wherein the limiting element is slidably mounted on the filter carrier.
37. An embolic protection device as claimed in claim 36 including stop means to limit the movement of the limiting element relative to the filter carrier.
- 25 38. An embolic protection device as claimed in claim 37 wherein the means to limit the movement of the limiting element comprises a pair of stops spaced axially apart along the filter carrier.

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39. An embolic protection device as claimed in claim 38 wherein the stops are provided by abutment surfaces formed on the filter carrier.
40. An embolic protection device as claimed in any of claims 32 to 39 wherein at least one limiting element is mounted to the filter element.
41. An embolic protection device as claimed in claim 40 wherein the limiting element is mounted to the filter element intermediate the proximal and distal ends of the filter element.
42. An embolic protection device as claimed in any of claims 32 to 41 wherein at least one limiting element is stiff relative to the filter carrier.
43. An embolic protection device as claimed in any of claims 32 to 42 wherein at least one limiting element is compliant relative to the filter carrier.
44. An embolic protection device as claimed in claim 40 wherein the limiting element is mounted to the filter element at the proximal end of the filter element.
45. An embolic protection device as claimed in any of claims 32 to 44 wherein the filter carrier is a guidewire.
46. An embolic protection device as claimed in claim 45 wherein the distal end of the guidewire includes a guiding tip which may be substantially retracted into the filter element.
47. An embolic protection device substantially as hereinbefore described with reference to the accompanying drawings.

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48. A method for positioning a medical device in a body lumen comprising the steps of:-

5 providing a medical guidewire assembly as claimed in any of claims 1 to 31;

advancing the assembly into a body lumen with the guidewire tip extending distally of the medical device to a first location;

10 moving the medical device relative to the tip to advance the medical device to a second location which is distally advanced from the first location.

15 49. A method for positioning a medical device in a body lumen substantially as hereinbefore described with reference to the accompanying drawings.

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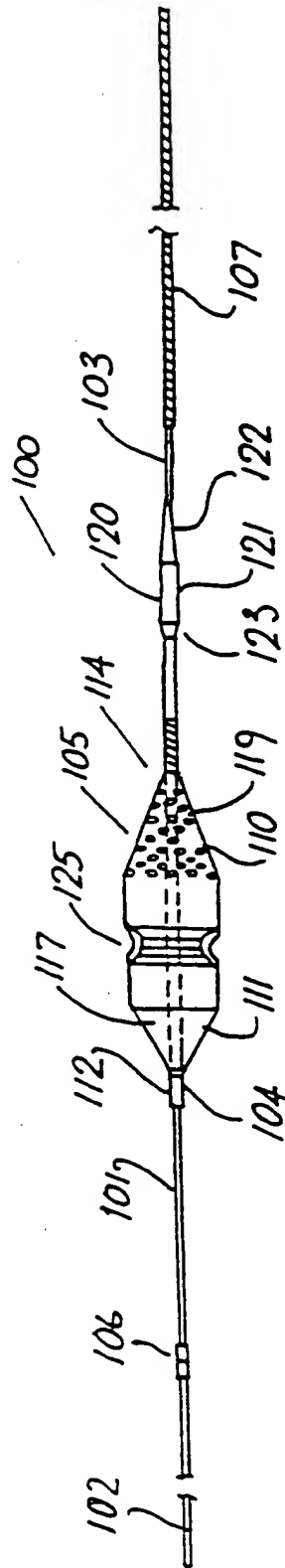


Fig.1

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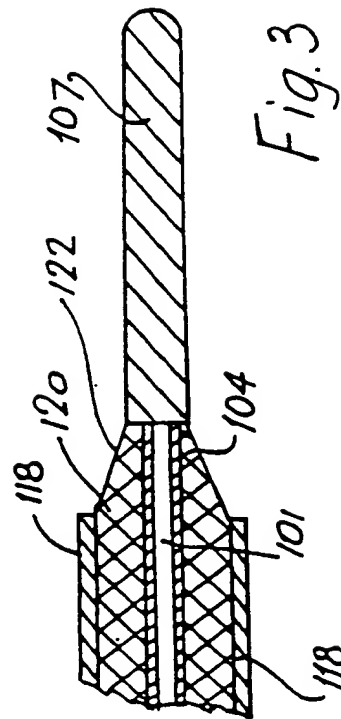


Fig. 3

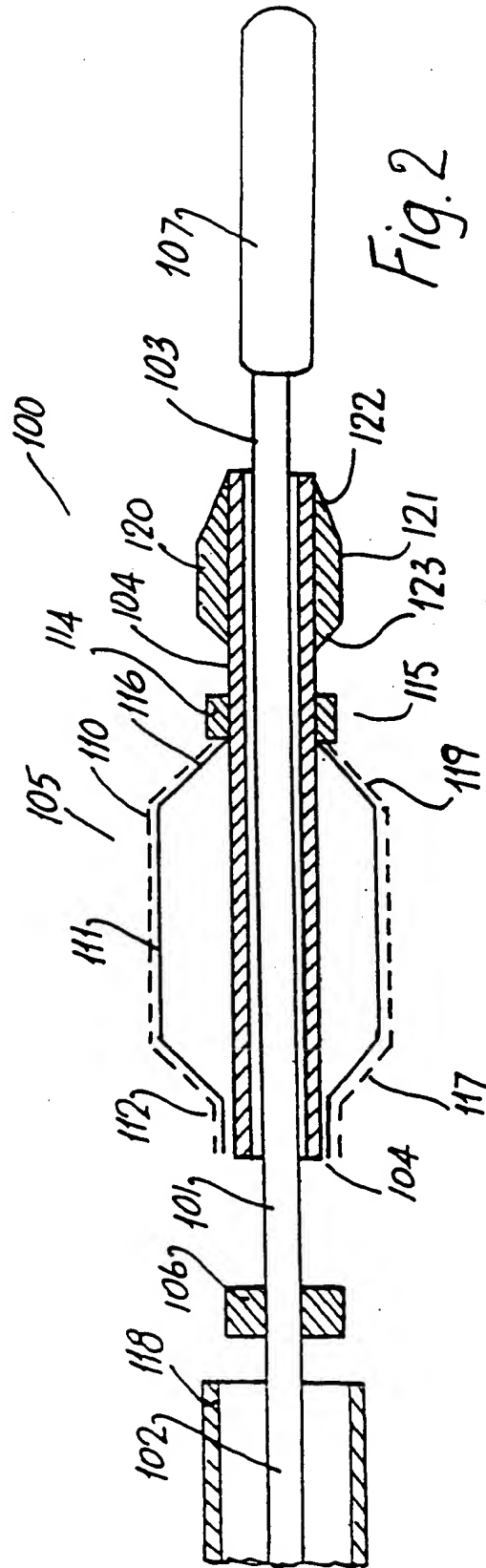
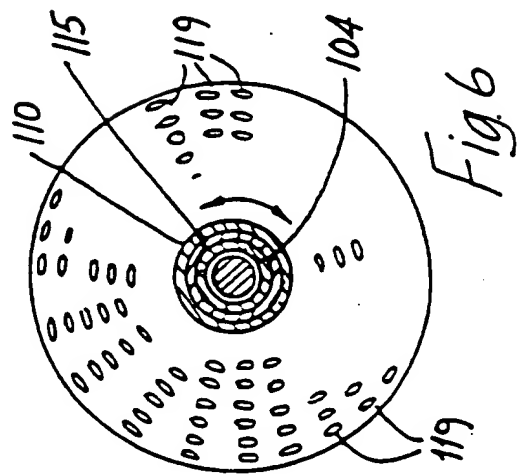
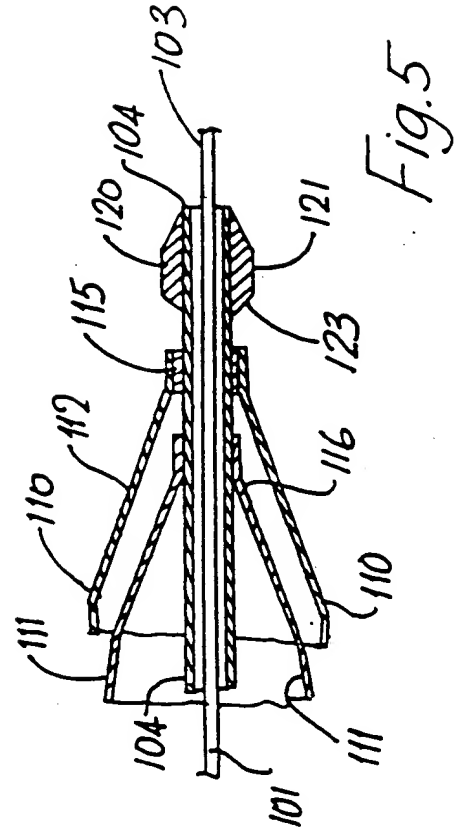
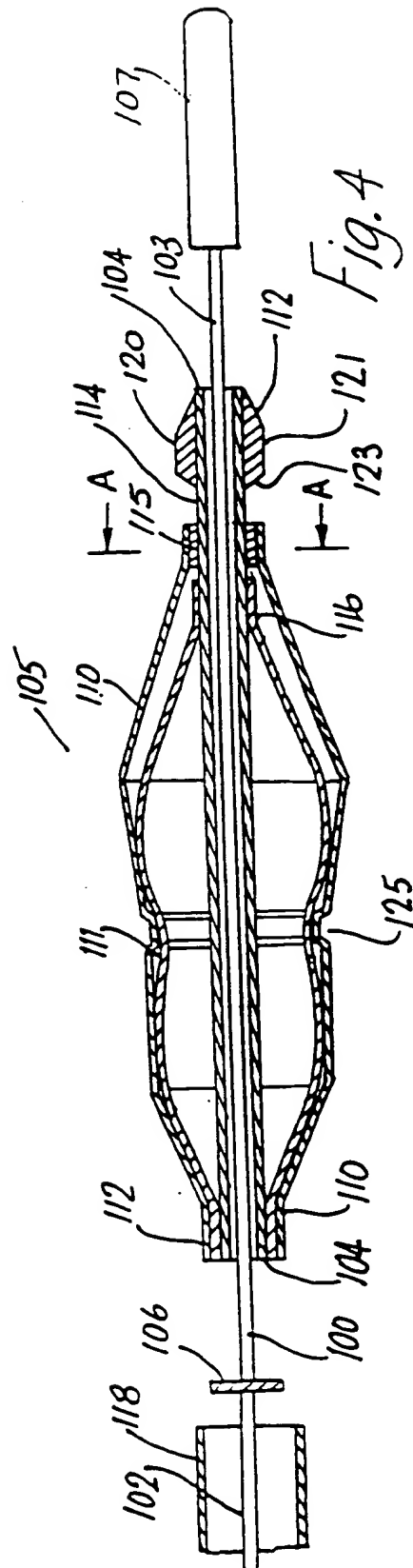
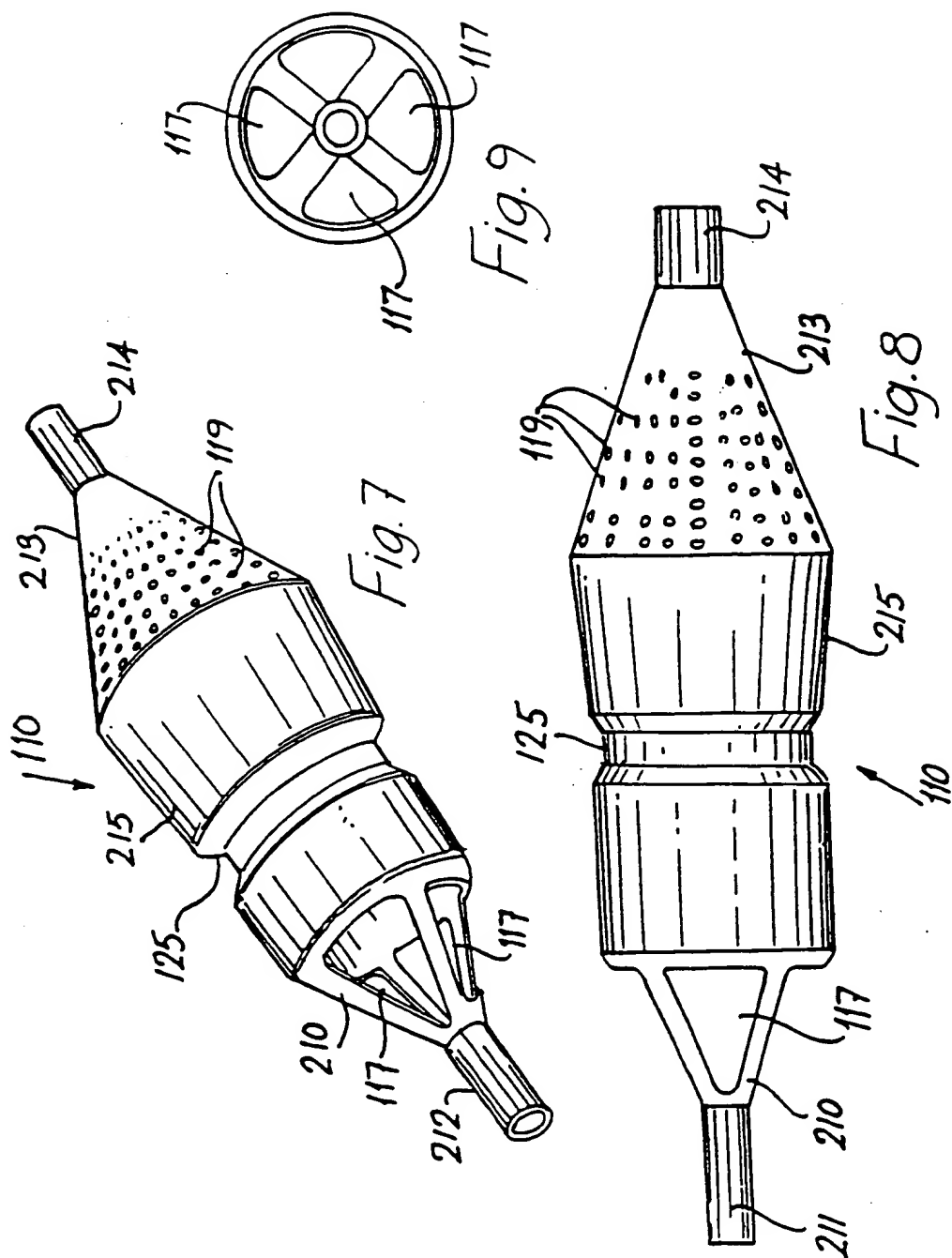


Fig. 2

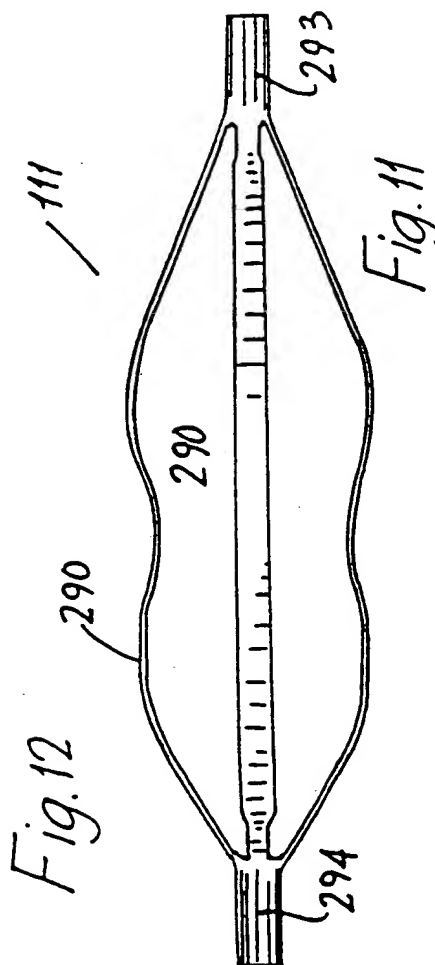
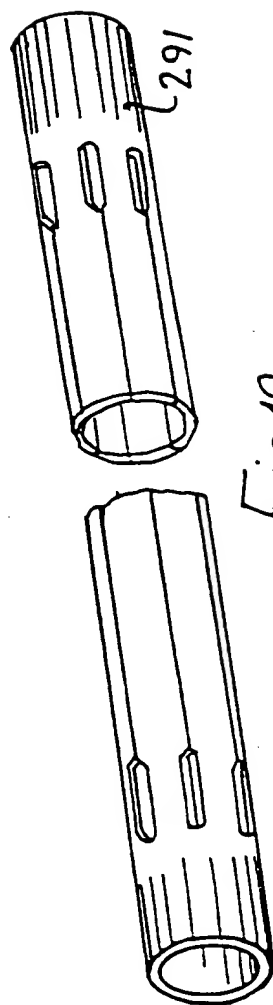
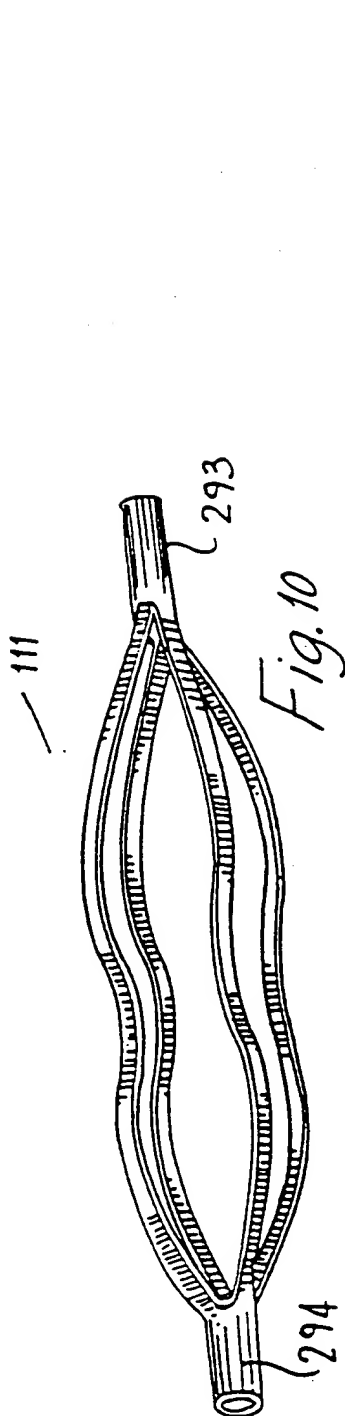
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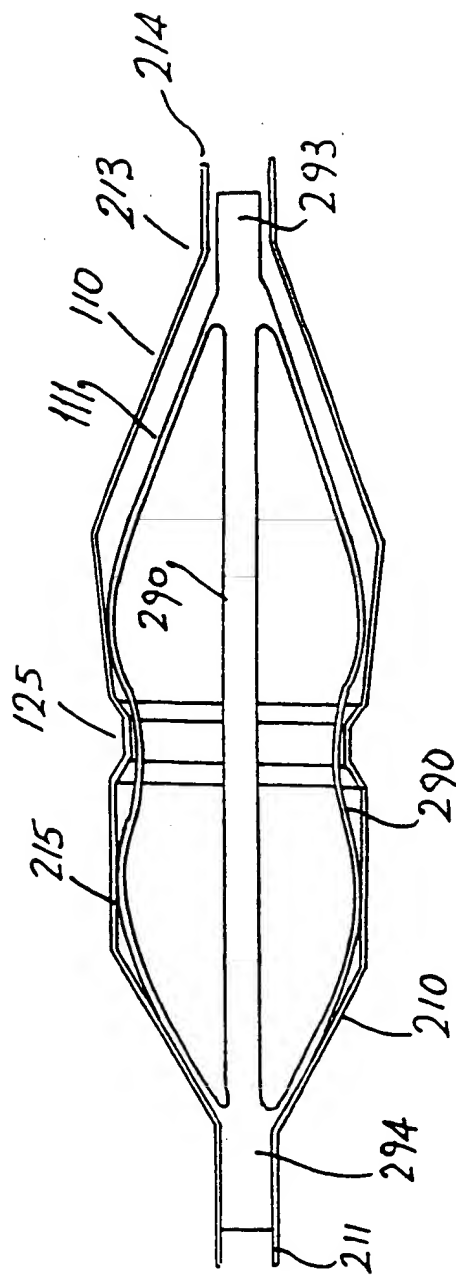
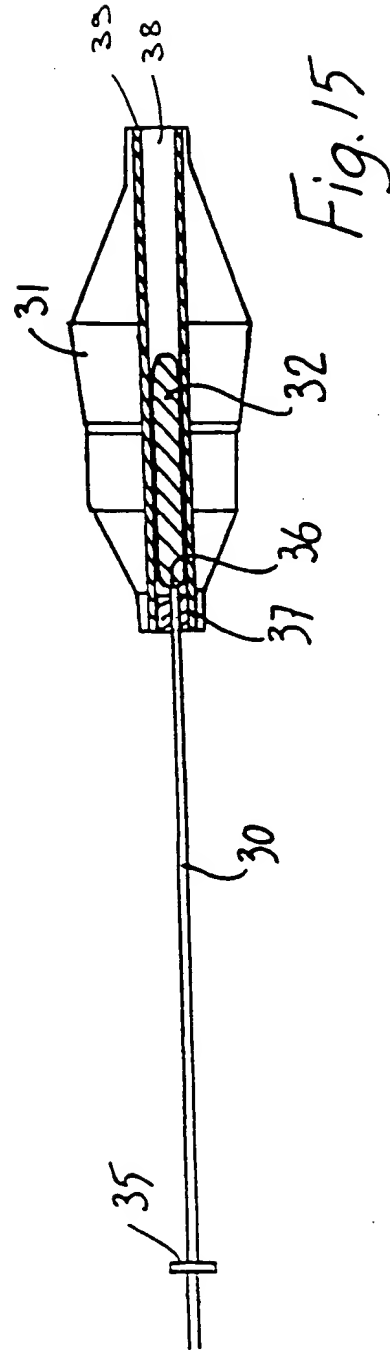
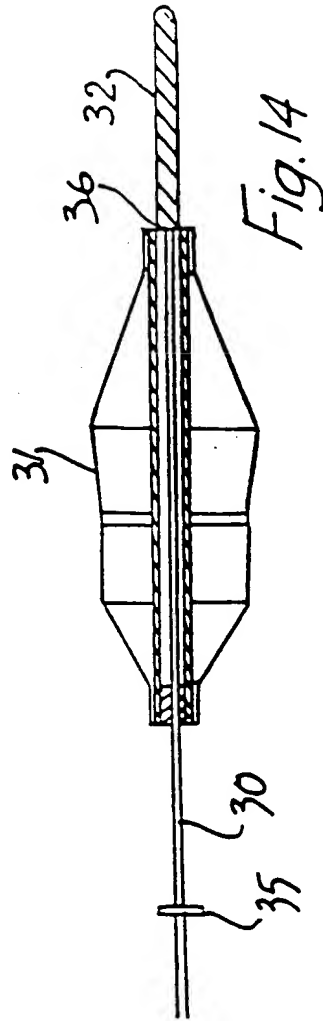
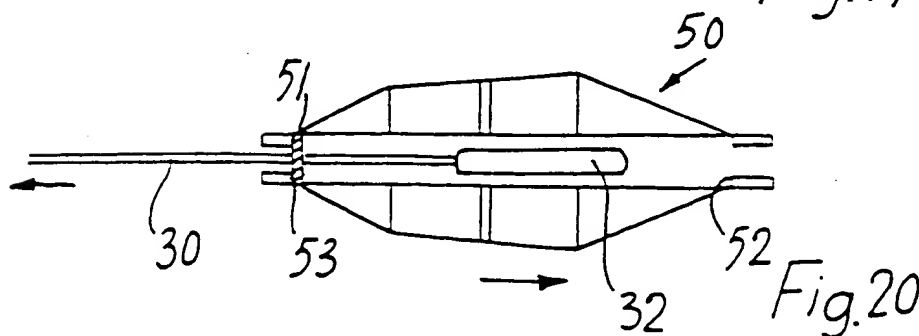
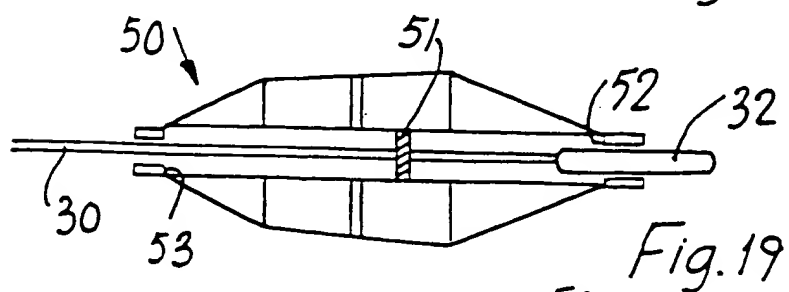
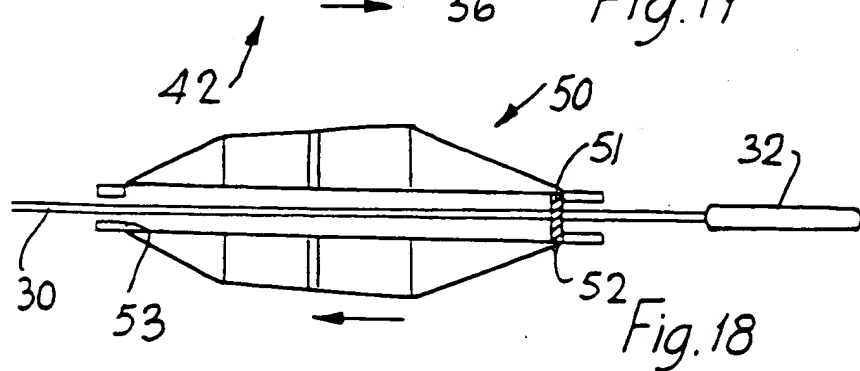
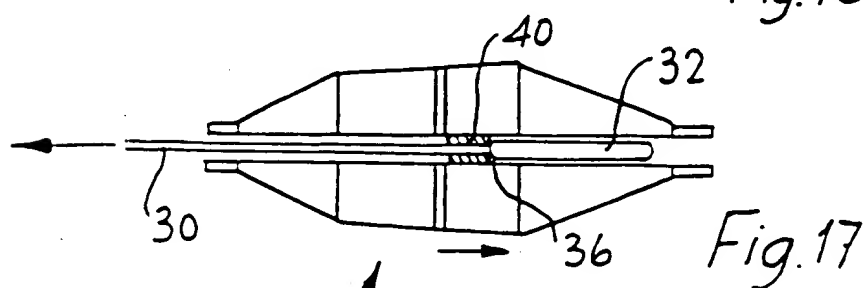
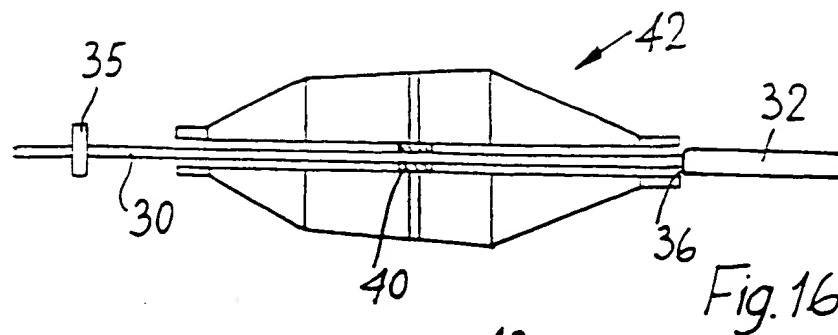


Fig. 13

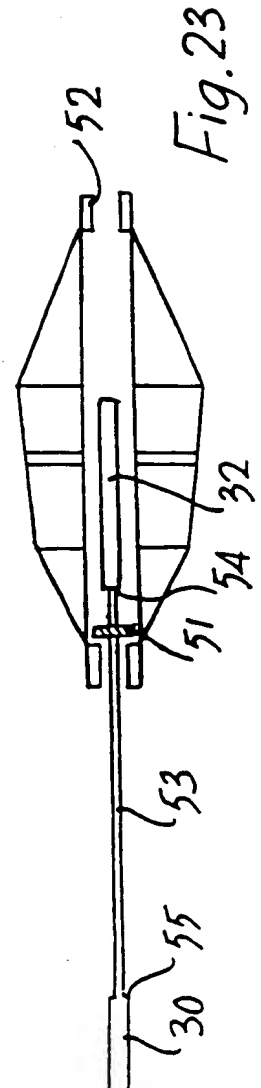
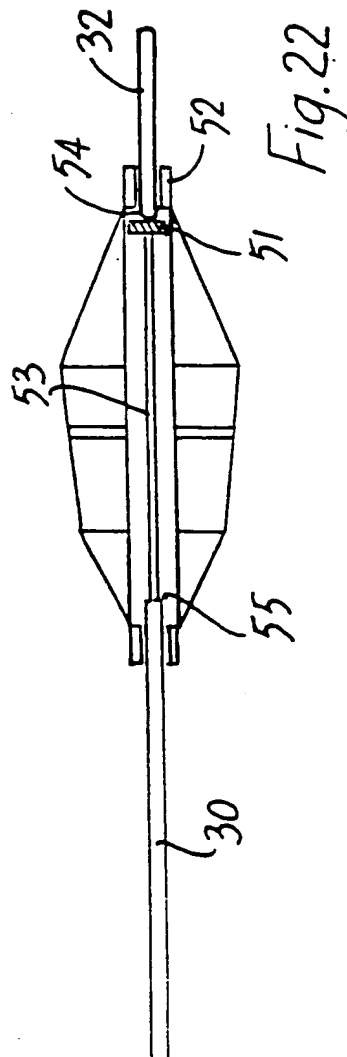
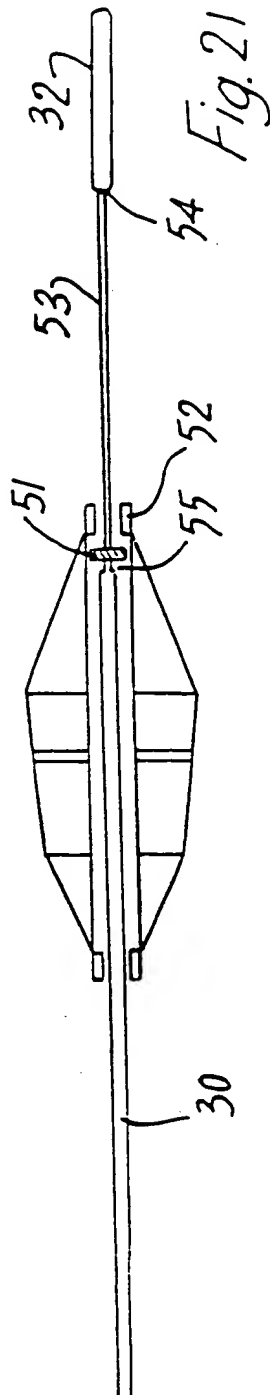
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